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This study evaluated the efficacy of a patient-spouse centered cognitive-affective counseling session (CARE: cognitive-affective reactions and expectations), to facilitate treatment decision-making for localized prostate cancer (PrCa). Methods: CARE identified treatment-related values and goals and focused on improving knowledge about treatment options. A time and attention matched General Health Information (GHI) session provided nutrition information. Couples (N=300) were enrolled after diagnosis with PrCa, but before a definite treatment decision was made. Data were assessed separately for patients and spouses at baseline, at 6-months, and at 12 months post intervention. Results: Both sessions were well accepted among participants. The goal of CARE to facilitate treatment decision making was best achieved for spouses and among those patient/partners who chose a non-invasive treatment option. Partners were more distressed about the treatment decision compared to patients, especially in the CARE condition and when considering invasive procedures. We interpret this result as an indication that participants in CARE processed the relevant information and that momentarily higher levels of distress were the "cost" of such processing. At 6-mo this effect disappears, underscoring its temporal nature. Conclusions: The results demonstrate the usefulness of integrating a brief counseling session into the decision-making process, and that increases in perceived difficulty of decision-making are short-term.

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INTRODUCTION:

The study evaluated an intervention designed to facilitate treatment decision making, adjustment, and coping among early-stage prostate cancer patients and their spouses/partners, in a randomized controlled trial. The intervention is based on the Cognitive-Social Health Information Processing (C-SHIP) framework that postulates that decision making is determined by cognitive factors (i.e., perceptions about vulnerability; expectancies and beliefs; values and goals), affective factors (i.e., concerns and worry about the disease and its treatment), as well as self-regulatory skills (i.e., the ability to manage distress and effectively execute recommended behaviors). The goal of the Cognitive and Affective Reactions and Expectations (CARE) Intervention is to facilitate treatment decision making by improving understanding of disease and treatment related facts, as well as by preparing the patient and his spouse/partner to anticipate the medical and psychological consequences of the disease and its treatment. This has been achieved in the context of a structured counseling session (approximate duration 45 min). Specifically, the patient's and spouse/partner's cognitive and emotional reactions to the following areas were explored: the treatment itself; potential side effects; long-term treatment success; relationship with others; and stress-management strategies. The efficacy of the intervention was evaluated systematically with a General Health Intervention (GHI) session serving as a comparison condition, controlling for time and attention. In the GHI condition, patients (and their spouses/partners) received and discussed current recommendations for general health (i.e., nutrition and stress management) and explored their own attitudes, beliefs, and feelings on these topics with a health educator. Assessments were obtained at baseline, and 6 weeks later, to assess treatment decisions, and at 6 months and 12 months post baseline to assess long-term adjustment and coping.

BODY:

RESEARCH ACCOMPLISHMENTS:

The following are tasks taken from the approved Statement of Work

Year 3: Task 5

Accrual for our study ended at the end of June 2003. Our total accrual for the study was 459 couples. As of June 2003, our completion rate of CARE and GHI sessions was 74% with 300 sessions (CARE 150;GHI 150) completed out of 408 that were originally scheduled.

(A) Complete baseline assessments

Baseline questionnaires have been given to the 300 couples that completed a CARE or GHI session. We have received 244 baseline questionnaires (81%) from patients and 236 baselines (79%) from spouses/partners.

(B) Complete 6-month assessments

As of the end of August 2004, 6 month follow-up questionnaires had been sent to 234 patients and 230 spouses with 213 patients (91%) and 165 (72%) spouses/partners returning completed assessments.

(C) Complete 12-month assessments

The 12-month follow-up assessments were sent to 211 patients and 183 spouse/partners who remained active in the study. Of those sent, we received questionnaires from 184 patients (87%) and 166 spouse/partners (91%). These participants have completed all of the required assessments (baseline, 6-month and 12-month) for the study.

(D) All questionnaire data have been entered into the centralized database and have been checked for accuracy. Frequency information has been computed. All data collection is complete.

(E) Continue Data Analyses

Over the past year we have continued to explore the data set and to conduct analyses on the questionnaire data.

a) Data cleaning. We examine all accumulated data for accurateness by performing range and logical checks. In addition, we perform spot checks on 10% of all entered questionnaires to catch data entry mistakes. To date our data has been entered with 99% accuracy.

b) Scale construction. Scale construction is complete. Measures of negative affect, (i.e., POMS), CES-D depression, intrusion and avoidance (i.e., revised impact of event scale; RIES) and quality of life (QOL; FACT-P) have been constructed by combining the appropriate items into scales. The reliability values of these scales are uniformly high: POMS positive affect ($\alpha = .89$); POMS negative affect ($\alpha = .92$); CESD depression ($\alpha = .80$); RIES intrusion ($\alpha = .87$); RIES avoidance ($\alpha = .79$). For the FACT-P and its subscales we have obtained acceptable reliability values: FACT-P physical well being subscale ($\alpha = .75$); FACT-P social well-being subscales ($\alpha = .66$); FACT-P emotional well-being subscale ($\alpha = .73$); functional well-being ($\alpha = .88$); FACT-P prostate-specific additional concerns ($\alpha = .77$). We have not found any differences by intervention/comparison group on any these scales, suggesting that the randomization procedure has been successful.

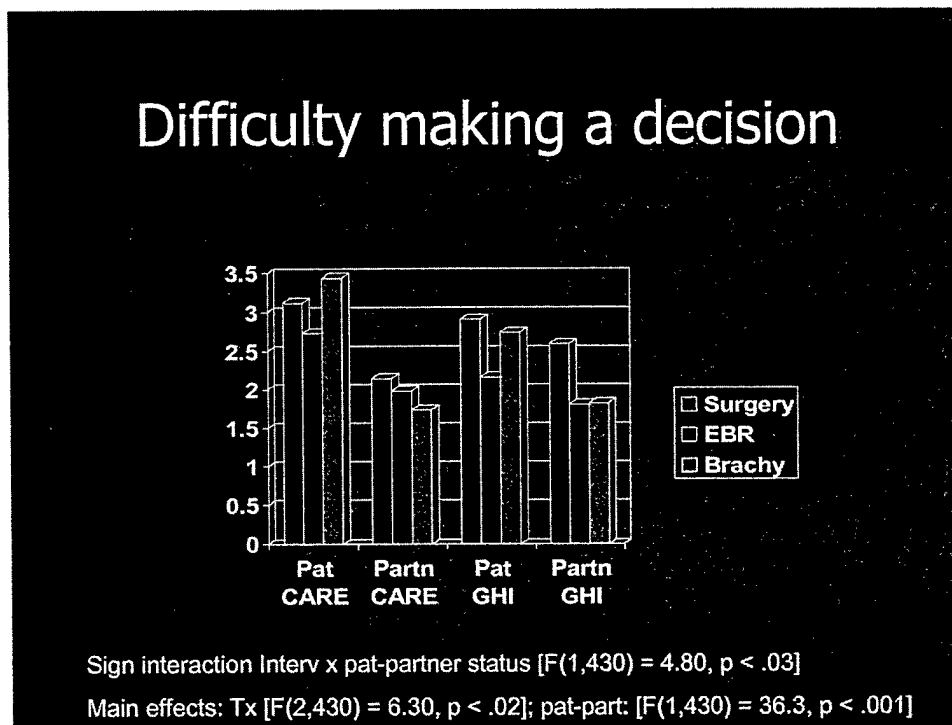
c) Description of sample. Patients are eligible to participate if they have been diagnosed with localized carcinoma of the prostate, and have not made a treatment decision. To date, we have received 244 baseline questionnaires from patients and 236 baselines from spouses/partners (total $N = 480$). Ninety percent of our sample is Caucasian, 9% is African American, and 1% is Hispanic or Asian-American. Half of the sample (52%) has at least a high school education, 25% completed college, and 17% have a post-graduate degree. Approximately half of the patients are retired (51%), 45% are employed, and 4% are disabled, unemployed, or semi-retired. Patients are on average 64 years old.

d) Evaluation of Intervention sessions. Upon agreeing to participate in the study, couples were randomized into the CARE or the GHI condition. Preliminary analyses of data assessing the acceptability and usefulness of these sessions suggest that both of the sessions are well accepted. For the CARE intervention, 62% of patients indicated that the session was quite a bit or very useful in understanding potential side-effects of prostate cancer treatment; 74% indicated that there was enough information to make a treatment decision; 76.5% thought the information about side-effects was above average, good, or excellent; 74% indicated that the discussion about treatment consequences was above average, good, or excellent; and 64% thought it provided a good or excellent forum to

hear the partner's treatment opinions. Most importantly, 71% of patients indicated that the information provided was useful for treatment decision making, that the information was very understandable (95%), and that the focus on patients' values and goals during the session was very important (74%). Overall, 44% rated the sessions as excellent, 35% as good; 6% as above average (the remaining 15% rated the sessions as average or poor (1.6%)).

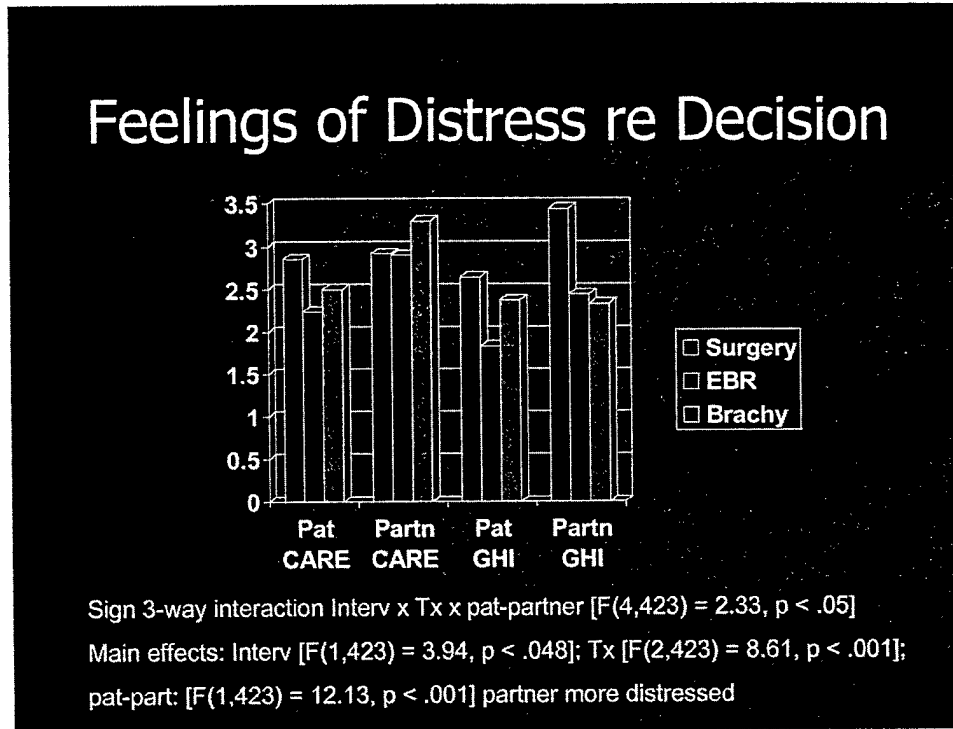
The GHI session that focused on nutritional needs during prostate cancer treatment was equally well accepted. Patients indicated that the session was quite a bit or very helpful in understanding the potential link between nutrition and prostate cancer (52%), and that it addressed concerns about nutrition quite a bit or very much (76%). Patients rated the nutritional information we provided with respect to specific treatment options very highly: for surgery (45% good to excellent); external beam radiation (52% good to excellent). Overall, 26% rated the sessions as excellent, 31% as good; 16% as above average (the remaining 27% rated the sessions as average or poor (9.1%)).

e) Efficacy of intervention. Based on analyses of the baseline data there were no differences by study group with regard to worry and distress about, and satisfaction with one's treatment decision. A three-factor analysis of variance (Intervention vs control; treatment (surgery, external beam radiation, brachytherapy; and patient/partner status) with treatment difficulty as the outcome variable, revealed that the CARE intervention worked best for spouses/partners to reduce perceived difficulty of decision making ($F(1,430) = 4.80, p < .03$; see figure 1).



With regard to chosen treatment, patients and spouses both found it more difficult to make a decision if it involved the more invasive surgical procedures (i.e., prostatectomy and brachytherapy; $F(2,430) = 6.30, p < .02$). Overall, however, patients found it more difficult to make a treatment decision compared to spouses ($F(1,430) = 36.3, p < .001$).

With regard to feelings of distress during the decision process, using the same multivariate analysis approach, we obtained a three-way interaction between Intervention type (CARE vs. GHI), treatment, and patient/partner status ($F(4,423) = 2.33, p < .05$; see figure below). We interpret this interaction as follows, partners felt higher levels of distress about the treatment decision, especially when they considered an invasive procedure such as surgery or brachytherapy and if they were randomized into the CARE condition.



These results are not entirely surprising, given the nature of the CARE intervention, which by reviewing all treatment related issues and connecting those issues to personal goals and values might have momentarily made the decision somewhat more distressing. We interpret this result as an indication that participants processed the relevant information and that increased perceived difficulty is the "cost" of such processing. When examining this variable at the 6-month assessment point, this difference disappears, further reinforcing that this was a temporary effect.

The emotionally taxing nature of the treatment decision is also reflected in elevated levels of worry about the decision. We found a significant main effect for worry about the decision among patients who chose surgery as a treatment ($F(1,427) = 3.22, p < .037$). Additionally, we found higher levels of worry among patients compared to partners, as expressed by a significant main effect of patient/partner status with regard to worry about treatment decision ($F(1,427) = 5.40, p < .021$).

We next examined the long-term effects of the CARE/GHI sessions on the treatment decision variables using data collected at the 6-mo assessment point. The study group

differences for the variable indicating that a decision was difficult disappeared. Thus, the issues that influenced treatment decision did not persist. Still, patients, compared to their partners, perceived the decision as more difficult, six months after diagnosis and independent from study group ($F(1,400) = 4.02, p < .046$). Similarly, the differences in distress by study group that were found at baseline, disappeared. The only difference that persisted were significantly elevated perceived feelings of distress about the treatment decision among partners compared to patients ($F(1,404) = 15.83, p < .001$). Thus, even six months after diagnosis, patients found the treatment decision more difficult, but their partners showed higher levels of distress about the decision.

At 6-months, patients were significantly more likely to endorse the belief that they would choose their treatment again, compared to their partners ($F(1,400) = 4.02, p < .046$). In contrast, partners indicated that they were significantly more satisfied with the treatment compared to patients ($F(1,366) = 4.97, p < .026$).

These results are currently being written up for publication.

OTHER ACCOMPLISHMENTS –YEAR 3:

Since accrual has ended for the study we have focused our efforts on maintaining the return rate for the follow-up assessments. Phone calls and postcards are continually used to remind participants to return the questionnaires. We also have developed a newsletter to keep participants informed about the study and to serve as a reminder to return the questionnaires.

KEY RESEARCH ACCOMPLISHMENTS:

- Continuation of baseline 6-month and 12-month assessments
- Successful return rates for patient and spouse 6-month and 12-month assessments
- Data analysis
- Presentation of results to two national conferences

REPORTABLE OUTCOMES:

Based on our data analyses of the baseline data set we had two accepted presentations at the annual meetings of the American Society of Preventive Oncology (ASPO) and the Society of Behavioral Medicine (SBM) in 2004.

Diefenbach, M.A., Dorsey, J.D., Horwitz, E., Uzzo, R., Greenberg, R., Pollack, A., Raysor, S., Gillespie, D. (2004, March). Treatment decisions among prostate cancer patients and spouses: results from a randomized trial. Presentation at 28th Annual Meeting of the American Society of Preventative Oncology, Bethesda, MD

Diefenbach, M.A., Dorsey, J.D., Horwitz, E., Uzzo, R., Greenberg, R., Pollack, A., Raysor, S., Gillespie, D. (2004, March). A patient-spouse centered intervention to facilitate treatment decision making for localized prostate cancer: results from a randomized trial. Presentation at the 25th Annual Meeting of the Society of Behavioral Medicine, Baltimore, MD

CONCLUSIONS:

We have used the third year to complete baseline data collection and continue to obtain follow-up assessments. By the end of the active recruitment phase we conducted 300 CARE or GHI sessions. Questionnaires were processed, entered in the database, verified, and cleaned. We have conducted data analysis and have found promising results that underscore the efficacy of our intervention. These results were presented at two national conferences. Our efforts for the final 6 month in no-cost extension will focus on disseminating study results through publications of manuscripts.

REFERENCES:

None

APPENDICES:

None